EXHIBIT A

November 2006

Guidance for Industry

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

Additional copies are available from:
Office of Plant and Dairy Foods, HFS-300
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2022
http://www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
November 2006

Guidance for Industry [1]

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

This guidance document represents the Food and Drug Administration's (FDA's)

current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance provides a recommended maximum lead level of 0.1 ppm in candy[2] likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients and to be protective of human health. For additional discussion of the background and rationale underlying this recommended level, see "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children."

In addition to announcing the recommended maximum lead level, FDA as explained below, is rescinding the previous 0.5 ppm guideline for considering enforcement action against candy products likely to be consumed frequently by small children. FDA is prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. Further, FDA is reiterating its enforcement policy toward the use of lead-based ink on candy wrappers as originally stated in its 1995 letter to the industry on this subject.

FDA considers the issuance of this guidance to be a prudent public health measure consistent with the Agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

A. Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is recommending that lead levels in candy products likely to be consumed frequently by small children not exceed 0.1 ppm because such levels are achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects. This recommended maximum level of 0.1 ppm for lead in candy likely to be consumed frequently by small children is consistent with the FDA's longstanding goal of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained. This recommendation is further discussed in the supporting document for

this guidance noted above.

B. Enforcement Policy for Lead in Candy Likely To Be Consumed Frequently by Small Children

Because it is no longer regarded as consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products by small children could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm.

FDA is now prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy, including the level of lead present, the best available consumption data, and the lead exposure that would result from consumption of the product.

C. Enforcement Policy for Use of Lead-Based Inks on Candy Wrappers

FDA is reiterating in this guidance that FDA's policy toward the use of lead-based ink on candy wrappers remains as stated in its 1995 letter to the industry on this subject:

> Generally speaking, if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food.

Suitable non-lead-based printing inks[3] are widely available for use in food packaging, and we continue to strongly urge all candy manufacturers, including those whose products are offered for import into this country, to refrain from the use of lead-based printing inks on their packaging materials.

In addition, the use of lead-based printing inks on candy wrappers may subject a firm to regulatory action by the U.S. Consumer Product Safety Commission under the Federal Hazardous Substances Act (see Letter to US candy importers - July 9, 2004 (PDF) and Letter to candy producers in Mexico (English version) - July 12, 2004 (PDF) for additional information). Furthermore, the use of lead or lead-based inks in or on packaging, including candy wrappers, is subject to state Toxics in Packaging legislation which has been enacted in nineteen U.S. states, (see Toxics in Packaging Clearinghouse Fact Sheet (PDF) for additional information).

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[1] This guidance has been prepared by the Office of Plant and Dairy Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] We have included within the broad category of candy, "Mexican-style" candy. "Mexican style" refers to candy which contains ingredients popular in Mexico, such as chili and tamarind, which are not typically found in domestic candy in the U.S. Within the category of "Mexican-style" candy, we have included powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

[3] Non-lead based printing inks may contain incidental lead at trace levels, e.g., < 0.001%, but, do not contain intentionally added lead as would for example lead chromate inks, which can contain > 2% lead.

Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children October 2006

Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers June 13, 1995

Consumer Product Safety Commission: Letter to U.S. Candy Importers (available in PDF) July 9, 2004

Consumer Product Safety Commission: Letter to Candy Producers in Mexico (available in PDF) July 12, 2004

Toxics in Packaging Clearinghouse Fact Sheet (available in PDF) January 2005

This document supercedes "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," December 2005

EXHIBIT B

CFSAN/Office of Cosmetics and Colors
December 27, 2007

Lipstick and Lead: Questions and Answers

The Food and Drug Administration (FDA) has received a number of inquiries regarding reports of levels of lead in lipstick. The following information is drawn from responses to those inquiries.

What is FDA's legal authority over cosmetics?

FDA regulates cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Act does not subject cosmetics to pre-market approval by FDA, with the exception of most color additives. It does, however, require that cosmetics marketed in interstate commerce be safe when used as directed in the labeling or under customary conditions of use. The FD&C Act subjects all color additives (other than coal-tar hair dyes) used in FDA-regulated products, including those used in lipstick, to pre-market approval. The listing regulation for each approved color additive includes limits for trace levels of heavy metal contaminants, if appropriate. FDA can and does take action against firms and individuals who violate the law, as determined by public health priorities and resources. To learn more on this subject, please refer to FDA Authority Over Cosmetics.

Has FDA been aware of concerns about lead in lipstick?

Reports about lead in lipstick are not new. In the 1990s, reports of analytical results from a commercial testing laboratory suggested that traces of lead in lipstick might be of concern. Subsequent evaluation by FDA of that laboratory's test results determined that an unvalidated and inappropriate testing method had been used. FDA's analyses did not detect levels of lead that would be considered harmful. The levels found did not exceed trace

amounts that would be unavoidable even under conditions of good manufacturing practice, given background levels in the environment.

Has FDA published tolerance levels for lead in lipstick?

FDA has not published tolerance levels for contaminants, such as lead, in cosmetics. However, FDA does set specifications for impurities, such as lead, for color additives used in cosmetics. In addition, as noted above, cosmetics must by law be safe when used as directed in the labeling or under customary conditions of use.

It's been reported that levels of lead in certain lipstick exceed those for candy. Is this a fair comparison?

FDA has yet to confirm the latest reports. However, it is not valid to compare the FDA-recommended level for lead in candy, a product intended for ingestion and which may be consumed on a regular basis, with lead levels in lipstick, a product intended for topical use and which is ingested in much smaller quantities than candy.

Is FDA following up on the latest reports?

Because allegations regarding lead in lipstick surface periodically, and because of the amount of time since FDA last surveyed lipsticks in the marketplace, FDA has decided to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market. FDA has obtained commercial samples of the same lipstick brands cited in the recent report. FDA laboratories have been adapting a previously validated, state-of-the-art method to do the analyses.

Does FDA intend to take enforcement action, given the latest report?

As a science-based public health agency, FDA bases its actions upon authoritative scientific evidence and the agency's authority under the law. FDA takes seriously its commitment to develop and implement policies that will promote consumer safety and enhance public health. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its options under the authority of the FD&C Act in protecting the health and welfare of consumers.

EXHIBIT C

CFSAN/Office of Cosmetics and Colors
January 24, 2006; Revised April 20, 2007

Color Additives and Cosmetics

More information on
- Color Additives
- Color Additives and Cosmetics

Color additives are subject to a strict system of approval under U.S. law [FD&C Act, sec. 721; 21 U.S.C. 379e]. Except in the case of coal-tar hair dyes, failure to meet U.S. color additive requirements causes a cosmetic to be adulterated [FD&C Act, sec. 601(e); 21 U.S. Code 361(e)]. Color additive violations are a common reason for detaining imported cosmetic products offered for entry into this country.

Some Basic Requirements

If your product (except coal-tar hair dyes) contains a color additive, by law [FD&C Act, Sec. 721; 21 U.S.C. 379e; 21 CFR Parts 70 and 80] you must adhere to requirements for:

- **Approval.** All color additives used in cosmetics (or any other FDA-regulated product) must be approved by FDA. There must be a regulation specifically addressing a substance's use as a color additive, specifications, and restrictions.
- **Certification.** In addition to approval, a number of color additives must be batch certified by FDA if they are to be used in cosmetics (or any other FDA-regulated product) marketed in the U.S.
- **Identity and specifications.** All color additives must meet the requirements for identity and specifications stated in the Code of Federal Regulations (CFR).
- **Use and restrictions.** Color additives may be used only for the intended uses stated in the regulations that pertain to them. The regulations also specify other restrictions for certain colors, such as the maximum permissible concentration in the finished product.

How are color additives categorized?

The FD&C Act Section 721(c) [21 U.S. C. 379e(c)] and color additive regulations [21 CFR Parts 70 and 80] separate approved color additives into two main categories: those subject to certification (sometimes called "certifiable") and those exempt from certification. In addition, the regulations refer to other classifications, such as straight colors and lakes.

- **Colors subject to certification.** These color additives are derived primarily from petroleum and are sometimes known as "coal-tar dyes" or "synthetic-organic" colors. (**NOTE:** Coal-tar colors are materials consisting of one or more substances that either are made from coal-tar or can be derived from intermediates of the same identity as coal-tar intermediates. They may also include diluents or substrata. (See *Federal Register*, May 9,

1939, page 1922.) Today, most are made from petroleum.)
    - Except in the case of coal-tar hair dyes, these colors must not be used unless FDA has certified that the batch in question has passed analysis of its composition and purity in FDA's own labs. If the batch is not FDA-certified, don't use it.
    - These certified colors generally have three-part names. The names include a prefix FD&C, D&C, or External D&C; a color; and a number. An example is "FD&C Yellow No. 5." Certified colors also may be identified in cosmetic ingredient declarations by color and number alone, without a prefix (such as "Yellow 5").
- **Colors exempt from certification.** These color additives are obtained primarily from mineral, plant, or animal sources. They are not subject to batch certification requirements. However, they still are considered artificial colors, and when used in cosmetics or other FDA-regulated products, they must comply with the identity, specifications, uses, restrictions, and labeling requirements stated in the regulations [21 CFR 73].
- **Straight color.** "Straight color" refers to any color additive listed in 21 CFR 73, 74, and 81 [21 CFR 70.3(j)].
- **Lake.** A lake is a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by a simple mixing process [21 CFR 70.3(l)]. Because lakes are not soluble in water, they often are used when it is important to keep a color from "bleeding," as in lipstick. In some cases, special restrictions apply to their use. As with any color additive, it is important to check the Summary of Color Additives and the regulations themselves [21 CFR 82, Subparts B and C] to be sure you are using lakes only for their approved uses.

How can I guard against color additive violations?

Several precautions can help you avoid color additive violations that will cause your cosmetic to be adulterated:

- **Do not confuse certified colors with their uncertified counterparts.** For example, FD&C Yellow No. 5 is the certified form of tartrazine, and is approved for use in cosmetics generally. But tartrazine, which has not undergone FDA analysis and received FDA certification, must not be substituted for or identified in an ingredient declaration as FD&C Yellow No. 5.
- **Do not confuse certified colors with colors identified only by a Colour Index (CI) number, or by the E number sometimes used in European color identification.** You must not use a color subject to certification unless FDA has certified the batch in question [FD&C Act, sec. 721(a)(1)(A). A CI or E number does not indicate FDA certification.
- **When purchasing color additives subject to certification, check the label.** If the lot is certified, the color's label must state the legal name for the color (such as "FD&C Yellow No. 5"), or, if it is a mixture, the name of each ingredient; the FDA lot certification number; and the color's uses and restrictions as stated in the CFR [21 CFR 70.25).
- **Check the Summary of Color Additives on FDA's Web site.** Although this table is not a substitute for the regulations, it is an easy-to-use reference that introduces you to FDA-approved color additives and directs you to the regulations addressing specific color additives.
- **Become familiar with the regulations themselves.** The color additive regulations are in 21 CFR Parts 70 through 82. Specific color additives are addressed in Parts 73, 74, and

82. The color additive regulations are posted on FDA's Web site at http://www.cfsan.fda.gov/~dms/col-cfr.html. To purchase printed copies of the CFR by credit card, call the Government Printing Office at (202) 512-1800, Monday through Friday, from 8:00 a.m. to 4:00 p.m., Eastern Standard Time. To pay by check, write to the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Contact the Government Printing Office directly for current costs.

- **Confirm the status of color additives before use.** There may be changes in color additive approvals and changes in the uses and restrictions that apply to a color additive. Such changes may affect colors subject to certification as well as colors exempt from certification. To stay current with the regulations, you can check the latest edition of the CFR and FDA Dockets. You also may contact FDA at Color.Cert@fda.hhs.gov.
- **When purchasing colors subject to certification, confirm that the manufacturer has requested certification.** For example, you can choose a manufacturer from FDA's list of companies that have requested color certification within the past two years. This list is posted on FDA's Web site at http://www.cfsan.fda.gov/~dms/col-comp.html and is available as Document #710 by mail or fax through the Center for Food Safety and Applied Nutrition Outreach and Information Center's toll-free phone number, 1-888-SAFEFOOD. If the company that appears on the color additive label is not on this list, you may contact FDA at Color.Cert@fda.hhs.gov to determine whether the company has in fact requested certification of its color additives.

Must I match colors with intended use?

Yes. No matter whether a particular color is subject to certification or exempt from certification, U.S. law prohibits its use in cosmetics (or any other FDA-regulated product) unless it is approved specifically for the intended use [FD&C Act, sec. 721(a)(1)(A); 21 U.S.C. 379e(a)(1)(A)].

The regulations also restrict intended use as follows:

- **Eye-area use:** You may not use a color additive in the area of the eye unless the regulation for that additive specifically permits such use [21 CFR 70.5(a)]. The "area of the eye" includes "the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge" [21 CFR 70.3(s)]. Although there are color additives approved for use in products such as mascara and eyebrow pencils, none is approved for dyeing the eyebrows or eyelashes.
- **Externally applied cosmetics:** This term does not apply to the lips or any body surface covered by mucous membrane. For instance, if a color additive is approved for use in externally applied cosmetics, you may not use it in products such as lipsticks unless the regulation specifically permits this use [21 CFR 70.3 (v)].
- **Injection:** No color additive may be used in injections unless its listing in the regulations specifically provides for such use. This includes injection into the skin for tattooing or permanent makeup. The fact that a color additive is listed for any other use does not mean that it may be used for injections [21 CFR 70.5(b)]. There are no color additives listed in the regulations as approved for injections.

What about special effects and novelty use?

No matter how exotic or novel the color additive or its intended use, it is subject to the same regulations as the more everyday colors and products. The following items are a sampling of some out-of-the-ordinary color additives. This list is not exhaustive. Rather, it is intended to show how the regulations apply to such colors:

- **Color-changing pigments:** Colors that change in response to such factors as change in pH or exposure to oxygen or temperature are subject to the same regulations as all other color additives.
- **Composite pigments:** Color additives used in combination to achieve variable effects, such as those found in pearlescent products, are subject to the same regulations as all other color additives. Some color additives, when used in combination, may form new pigments, which may not be approved for the intended use. An example is a "holographic" glitter, consisting of aluminum an approved color additive bonded to an etched plastic film.
- **Fluorescent colors:** Only the following fluorescent colors are approved for use in cosmetics, and there are limits on their intended uses: D&C Orange No. 5, No. 10, and No. 11; and D&C Red No. 21, No. 22, No. 27, and No. 28 [21 CFR 74.2254, 74.2260, 74.2261, 74.2321, 74.2322, 74.2327, and 74.2328].
- **Glow-in-the-dark colors:** Luminescent zinc sulfide is the only approved glow-in-the-dark color additive [21 CFR 73.2995].
- **Halloween makeup:** These products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.
- **Liquid crystal colors:** These additives, which produce color motifs in a product through diffraction, are unapproved color additives. Their use in cosmetics is therefore illegal [FD&C Act, sec. 601(e); 21 U.S.C. 361(e)].
- **Tattoo pigments:** As noted above, no color additives are approved for injection into the skin, as in tattoos and permanent makeup.
- **Theatrical makeup:** Like Halloween makeup, these products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.

Color Additives | Cosmetics

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by bxm/ear/viv April 20, 2007

EXHIBIT D

HEALTH CONSULTATION

Exposure Investigation
Herculaneum Lead Smelter Site
(aka: Doe Run Lead Smelter)
Herculaneum, Jefferson County, Missouri

EPA Facility ID: MOD006266373

June 10, 2005

Prepared by

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry
and
Missouri Department of Health and Senior Services

Table of Contents

Abbreviations and Acronyms

ATSDR	Agency for Toxic Substances and Disease Registry
ACGIH	American Conference of Governmental Industrial Hygienists
CDC	Centers for Disease Control and Prevention
EI	exposure investigation
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
G	grams
MDHSS	Missouri Department of Health and Senior Services
NCEH	National Center for Environmental Health (CDC)
mg/kg/day	milligrams per kilogram (of body weight) per day
mL	milliliter
MRL	minimal risk level
ppm	parts per million
PTTIL	Provisional Total Tolerable Intake Level
USDA	U.S. Department of Agriculture
µg/L	micrograms per liter

vegetables were preferentially selected for testing because they tend to take up more cadmium (ATSDR 1999b). The risk posed by eating cadmium-containing produce would depend on the rate of consumption. For example, an adult (70 kg) might eat 1 cup of lettuce (56 grams) per day, the vegetable with the highest concentration of cadmium (US Dept. of Agriculture Database 2004).

Using the highest cadmium concentration of 0.391 ppm, which was detected in lettuce, the maximum cadmium ingestion rate for this scenario would be:

0.391 µg/g (ppm) x 56 grams ÷ 70 kg body weight = 0.3128 µg/kg/day

The result, 0.3128 µg/kg/day, is equivalent to 0.00031 mg/kg/day.

This estimated maximum cadmium dose slightly exceeds the ATSDR chronic MRL for cadmium of 0.0002 mg/kg/day. Exposure to a level above the MRL does not mean that adverse health effects will occur. MRLs serve as a screening tool to help public health professionals decide where to look more closely for potential heath risks. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

The ATSDR chronic MRL for cadmium is based on exposure for 365 days a year for many years. However, the participants in this investigation ate home-grown vegetables occasionally, during a few months of the year, so their average daily dose would be considerably less than the value calculated above. Because of the large surface area of lettuce, a portion of the cadmium concentration may result from surface deposition. Peeling and thoroughly washing vegetables would reduce the amount of surface metal contamination.

The consumption of these fruits and vegetables is not likely to result in adverse health problems from cadmium exposure if consumed occasionally for a few months each year. To be protective of public health, ATSDR recommends that individuals follow general food safety guidelines. Those include washing hands before preparing foods and washing foods before consumption. Peeling and thoroughly washing vegetables would reduce the amount of surface metal contamination.

Lead

Many plants can take up lead from the soil (ATSDR 1999a). Edible plants acquire lead from the soil through their roots, by direct foliage uptake, and by surface deposition of particulate matter (ATSDR 1999a). Lead generally deposits superficially on leaves, with less leaf penetration than cadmium (Vousta 1996). At significantly high levels, lead is poisonous to plants and can stunt plant growth.

The lead levels in vegetables and fruits tested ranged from 0.008 – 1.737 ppm. Green leafy vegetables tend to accumulate lead on the plant surface. Root vegetables take up

lead into the plant tissue (ATSDR 1999a; Finster et al. 2003). The risk posed by eating lead-containing produce depends on the frequency and amount of consumption. An ATSDR MRL for lead is not available. Therefore, the U.S. Food and Drug Administration (FDA) provisional tolerable lead intake levels were used.

The FDA's recommended Provisional Total Tolerable Intake Level (PTTIL) for lead in children less than 6 years of age is 6 µg lead/day. For children 7 years and older, the PTTIL is 15 µg lead/day. It increases to 75 µg lead/day for adults (USFDA 1993).

The maximum concentration of lead detected in a plant in this investigation—1.737 ppm—was detected in lettuce. Plants with higher surface areas (green leafy vegetables, such as lettuce, collard greens, polk wild greens and swiss chard) tend to have higher lead levels (Finster et al. 2003). Contaminated soil and dust attaches to the plant surface more easily and tends to remain on vegetables that are not washed well.

The risk posed by eating lead-containing produce would depend on the rate of consumption. For instance, an adult might eat 1 cup of lettuce (56 grams) per day (USDA 2004). Using the maximum lead level detected (1.737 ppm), an adult eating lettuce at that rate would ingest about 95 µg lead/day, which exceeds the adult PTTIL for lead. This ingestion estimate also exceeds the lead PTTIL for children. The other vegetables contained less than half the lead concentration found in lettuce. Most of the individuals who provided the home-grown fruits and vegetables only ate them when ripe and in season. This would result in a few months of occasional consumption each year.

Based on these assumptions, consumption of home-grown green leafy vegetables should be limited to a few times a week when in season. Lead content in lettuce, which has a large surface area, may partly result from deposition of lead-contaminated soil on the leaf surfaces.

To be protective of public health, ATSDR recommends that adults limit their consumption of green leafy vegetables to a few times a week when in season. Because young children and pregnant women are more sensitive to the effects of lead, they should avoid eating home-grown leafy vegetables. To reduce potential exposures to lead, home gardeners should preferentially plant fruiting vegetables instead of green leafy vegetables. Peeling and thoroughly washing vegetables can reduce the amount of lead contamination.

Reporting Results

In April 2004, individual test results and an explanation of their significance were provided to the participants of this investigation. An ATSDR physician was available to discuss participants' results.

EXHIBIT E

CFSAN/Office of Cosmetics and Colors
October 1991

COSMETIC LABELING MANUAL

CONTENTS

SUMMARY OF REGULATORY REQUIREMENTS FOR LABELING OF COSMETICS MARKETED IN THE UNITED STATES

Cosmetics marketed in the United States, whether manufactured here or imported from abroad, must be in compliance with the provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act, the Fair Packaging and Labeling (FP&L) Act, and the regulations published under the authority of these laws.

The regulations published by the Food and Drug Administration (FDA) are all codified in Title 21, Code of Federal Regulations (21 CFR). The regulations applicable to cosmetics are stated at 21 CFR, parts 700 to 740 (21 CFR 700 to 740). The color additive regulations applicable to cosmetics are found at 21 CFR 73, 74, 81 and 82.

The FD&C Act defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product. Soap products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body are not considered cosmetics under the law.

COSMETICS THAT ARE ALSO DRUGS

Products that are cosmetics but are also intended to treat or prevent disease, or affect the structure or functions of the human body, are considered also drugs and must comply with both the drug and cosmetic provisions of the law. Examples of products which are drugs as well as cosmetics are anticaries toothpastes (e.g., "fluoride" toothpastes), hormone creams, suntanning preparations intended to protect against sunburn, antiperspirants that are also deodorants, and antidandruff shampoos.

Most currently marketed cosmetics which are also drugs are over-the-counter drugs. Several are new drugs for which safety and effectiveness had to be proved to the agency before they could be marketed. A new drug is a drug which is not generally recognized by experts as safe and effective under the conditions of intended use or which has become so recognized but has not been used to a material extent or for a material time under such conditions.

The regulatory requirements for drugs are more extensive than the requirements applicable to cosmetics. For example, the FD&C Act requires that drug manufacturers register every year with the FDA and update their lists of all manufactured drugs twice annually. Additionally, drugs must be manufactured in accordance with current good manufacturing practice regulations as codified at 21 CFR 210 and 211.

ADULTERATED OR MISBRANDED COSMETICS

The FD&C Act prohibits the distribution of cosmetics which are adulterated or misbranded. A cosmetic is considered adulterated if it contains a substance which may make the product harmful to consumers under customary conditions of use; if it contains a filthy, putrid, or decomposed substance; if it is manufactured or held under insanitary conditions whereby it may have become contaminated with filth, or may have become harmful to consumers; or if it is not a hair dye and it contains a non-permitted color additive. Coal-tar hair dyes bearing on the label the caution statment prescribed by law and that give "patch-test" instructions are exempted from the adulteration provision even if they are irritating to the skin or are otherwise harmful to the human body. Eyelash and eyebrow dyes are not included in this exemption. All dyes used in eyelash and eyebrow dye products must be approved by the FDA for such use.

A cosmetic is misbranded if its labeling is false or misleading, if it does not bear the required labeling information, or if the container is made or filled in a deceptive manner.

COSMETIC LABELING

The cosmetics distributed in the United States must comply with the labeling regulations published by the FDA under the authority of the FD&C Act and the FP&L Act. Labeling means all labels and other written, printed or graphic matter on or accompanying a product. The label statements required under the authority of the FD&C Act must appear on the inside as well as any outside container or wrapper. FP&L Act requirements, e.g., ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container. The labeling requirements are codified at 21 CFR 701 and 740. Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with these

requirements may be considered misbranded and may be subject to regulatory action.

The principal display panel, i.e., the part of the label most likely displayed or examined under customary conditions of display for sale (21 CFR 701.10), must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container as prescribed by regulation. The net quantity of contents statement of a solid, semisolid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the U.S. gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity of contents is one pound or one pint or more, it must be expressed in ounces, followed in parenthesis () by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity of contents may additionally be stated in terms of the metric system of weights or measures.

The name and place of business of the firm marketing the product must be stated on an information panel of the label (21 CFR 701.12). The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for ....." or "Distributed by ....." or similar, appropriate wording.

The Tariff Act of 1930 requires that all imported articles state on the label the English name of the country of origin.

DECLARATION OF INGREDIENTS

Cosmetics produced or distributed for retail sale to consumers for their personal care are required to bear an ingredient declaration (21 CFR 701.3). Cosmetics not customarily distributed for retail sale, e.g., hair preparations or make-up products used by professionals on customers at their establishments and skin cleansing or emollient creams used by persons at their places of work, are exempt from this requirement provided these products are not also sold to consumers at professional establishments or workplaces for their consumption at home.

The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information panel of the package, i.e., the folding carton, box wrapping if the immediate container is so packaged, and may also appear on a firmly affixed tag, tape or card. The letters must not be less than 1/16 of an inch in height (21 CFR 701.3 (b)). If the total package surface available to bear labeling is less than 12 square inches, the letters must not be less than 1/32 of an inch in height (21 CFR 701.3(p)). Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, it is not enclosed in a folding carton, and the package surface area is less than 12 square inches (21 CFR 701.3(i)).

The ingredients must be declared in descending order of predominance. Color additives (21

CFR 701.3(f)(3)) and ingredients present at one percent or less (21 CFR 701.3(f)(2)) may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (21 CFR 701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients" (21 CFR 701.3(a)).

Cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)" before listing the cosmetic ingredients (21 CFR 701.3(d)).

All label statements required by regulation must be in the English language and must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase (21 CFR 701.2).

LABEL WARNINGS

Cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use. The statements must be prominent and conspicuous. Some cosmetics must bear label warnings or cautions prescribed by regulation (21 CFR 740). Cosmetics in self-pressurized containers (aerosol products), feminine deodorant sprays, and children's bubble bath products are examples of products requiring such statements.

Although the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement: Warning--The safety of this product has not been determined. Sec. 21 CFR 740.10.

TAMPER - RESISTANT PACKAGING

Liquid oral hygiene products (e.g., mouthwashes, fresheners) and all cosmetic vaginal products (e.g., douches, tablets) must be packaged in tamper-resistant packages when sold at retail. A package is considered tamper resistant if it has an indicator or barrier to entry (e.g., shrink or tape seal, sealed carton, tube or pouch, aerosol container) which, if breached or missing, alerts a consumer that tampering has occurred. The indicator must be distinctive by design (breakable cap, blister) or appearance (logo, vignette, other illustration) to preclude substitution. The tamper-resistant feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper-resistant feature. This statement must remain unaffected if the tamper-resistant feature is breached or missing. Sec. 21 CFR 700.25.

LAW ENFORCEMENT AUTHORITY

For enforcement of the law, the FDA may conduct examinations and investigations of products, inspect establishments in which products are manufactured or held, and seize adulterated (harmful) or misbranded (incorrectly or deceptively labeled or filled) cosmetics. Adulterated or misbranded foreign products may be refused entry into the United States. To prevent further shipment of an adulterated or misbranded product, the agency may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative

cosmetic. The FDA may also initiate criminal action against a person violating the law. Examples of products seized in recent years are nail preparations containing methyl methacrylate or formaldehyde, various eyebrow and eyelash dye products containing prohibited coal-tar dyes, and products contaminated with harmful microorganisms.

Further questions regarding regulatory requirements for marketing cosmetics should be directed to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors (HFS-100), 5100 Paint Branch Parkway, College Park, MD 20740, (301) 436-1130. Questions regarding requirements for marketing products which are also drugs should also be addressed to the Division of Drug Information, 5600 Fishers Lane, HFD-240, Rockville, MD 20857; telephone (301) 827-4570; email: druginfo@cder.fda.gov; Web site: http://www.fda.gov/cder/Offices/DDI/default.htm.

NOTE

Copies of the Code of Federal Regulations may be purchased by check or money order from the GOVERNMENT PRINTING OFFICE, WASHINGTON, DC 20402, telephone (202) 512-1800. Contact the Government Printing Office directly for current costs.

For general regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act, as well as for color additive regulations, order TITLE 21, CODE OF FEDERAL REGULATION, PART 1 TO 99.

For regulations applicable to cosmetics, including labeling regulations, order TITLE 21, CODE OF FEDERAL REGULATIONS, PART 600 TO 799.

Title 21 of the Code of Federal Regulations is updated each year in April with the regulations published during the year in the Federal Register.

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Cosmetics

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EXHIBIT F

LEXSEE 1998 U.S. DIST. LEXIS 9175

AT&T CORPORATION, et al., Plaintiffs, v. AMERITECH CORPORATION, Defendant.

98 C 2993

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

1998 U.S. Dist. LEXIS 9175

June 9, 1998, Decided
June 10, 1998, Docketed

DISPOSITION: [*1] Defendant's motion to dismiss plaintiff's claims (# 6-1 & # 9-1)) denied. AT & T's motion to refer issues arising from the Ameritech/Qwest alliance to the FCC granted. Matters referred to the FCC and action stayed. Court terminated the referral of AT & T's motion for a preliminary injunction and discovery matters to Magistrate Guzman. AT & T's renewed motion for a preliminary injunction denied.

CASE SUMMARY:

PROCEDURAL POSTURE: The cause was before the court upon the motion of plaintiffs, telecommunication corporations, to vacate the court's prior referral of their motion for a preliminary injunction to the magistrate, immediately grant the motion, and refer issues arising under an alliance between defendant telephone company and another telephone company to the Federal Communications Commission (FCC).

OVERVIEW: The court referred the question regarding the alliance or teaming arrangement between telephone companies to the FCC under the doctrine of primary jurisdiction. The court held that resolution of the issues involving *Sections 251(g)* and *271* of the Communications Act of 1934, codified at *47 U.S.C.S. §§ 251(g)* and *271 (Act)*, as amended by the Telecommunications Act of 1996, was placed within the special competence of the FCC and judicial process was suspended pending referral of those issues. Further, referral to the FCC would ensure uniformity and consistency in the regulation of businesses entrusted to the FCC and would promote a uniform and expert administration of the regulatory scheme under the Act. The court stated that it would be able to render a more informed decision by the referral, and the administration of justice favored referral. Next, the court held that it had the power to grant injunctive relief here, but declined to do so because it had referred the matter to the FCC. Also, the action would be stayed, rather than dismissed.

OUTCOME: The court granted the telecommunication companies' motion to refer issues arising from the alliance to the FCC. The matter was stayed until further court order. Also, the court terminated the referral of telecommunication companies' motion for a preliminary injunction and discovery matters to the magistrate, and their renewed motion for a preliminary injunction was denied.

LexisNexis(R) Headnotes

Administrative Law > Judicial Review > Reviewability > Jurisdiction & Venue
Administrative Law > Separation of Powers > Primary Jurisdiction

[HN1] Primary jurisdiction applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body.

Administrative Law > Judicial Review > Reviewability > Jurisdiction & Venue
Administrative Law > Separation of Powers > Primary Jurisdiction
Civil Procedure > Jurisdiction > General Overview
[HN2] In every case referred under the doctrine of primary jurisdiction, the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation. When deciding whether the doctrine of primary jurisdiction applies, courts consider whether: (1) the issue presented is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise, and whether the issue presented is particularly within the agency's discretion; (2) whether a substantial danger of inconsistent rulings exists if the matter is not referred; and (3) whether the administration of justice favors referral. Courts are to balance the advantages of applying the doctrine against the potential costs arising from delays in proceedings before the agency.

Administrative Law > Judicial Review > Reviewability > Jurisdiction & Venue
Civil Procedure > Judicial Officers > Judges > Discretion
Governments > Legislation > Interpretation
[HN3] Statutory interpretation is within the conventional experience of judges. Nevertheless, if a case raises questions of fact outside the conventional experience of judges or involves the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over.

Administrative Law > Agency Adjudication > Decisions > General Overview
Administrative Law > Judicial Review > Reviewability > Jurisdiction & Venue
Administrative Law > Separation of Powers > Primary Jurisdiction
[HN4] Referring a case to an agency under the doctrine of primary jurisdiction simply allows the court to consider the agency's views when rendering its decision; it does not shift the power to determine a federal lawsuit to an administrative agency.

Administrative Law > Separation of Powers > Primary Jurisdiction
Civil Procedure > Judgments > Relief From Judgment > General Overview
Civil Procedure > Remedies > Injunctions > General Overview
[HN5] The doctrine of primary jurisdiction affects the wisdom of entering injunctive relief prior to agency action. It does not, however, deprive the court of the power to order injunctive relief. Nevertheless, courts should generally avoid expressing a view on the merits when referring a case to an agency under the primary jurisdiction doctrine.

Communications Law > Federal Acts > Communications Act > General Overview
Communications Law > Federal Acts > Telecommunications Act > General Overview
[HN6] The Federal Communications Commission has the authority to issue interim injunctive relief. *47 U.S.C.S. § 154(i).*

Administrative Law > Separation of Powers > Jurisdiction
Administrative Law > Separation of Powers > Primary Jurisdiction
Civil Procedure > Dismissals > General Overview
[HN7] A court may, in its discretion, stay proceedings and retain jurisdiction pending determination by an administrative agency pursuant to the doctrine of primary jurisdiction. If the parties would not be unfairly disadvantaged, the court may also dismiss the case without prejudice.

COUNSEL: For AT&T CORPORATION, plaintiff: William F. Conlon, Ellen Sue Robbins, David W. Carpenter, Sidley & Austin, Chicago, IL.

For MCI TELECOMMUNICATIONS CORPORATION, plaintiff: Darryl Mark Bradford, John J. Hamill, Jr., Jenner & Block, Chicago, IL.

For MCI TELECOMMUNICATIONS CORPORATION, plaintiff: Jerome L Epstein, Jenner & Block, Washington, DC.

For ASSOCIATION FOR LOCAL TELECOMMUNICATIONS SERVICES, MCLEODUSA TELECOMMUNICATIONS SERVICES INC, FOCAL COMMUNICATIONS CORPORATION,

KMC TELECOM II INC, NEXTLINK COMMUNICATIONS INC, plaintiffs: Anne T. Bottini, Swidler & Berlin, Washington, DC.

For ASSOCIATION FOR LOCAL TELECOMMUNICATIONS SERVICES, MCLEODUSA TELECOMMUNICATIONS SERVICES INC, FOCAL COMMUNICATIONS CORPORATION, KMC TELECOM II INC, NEXTLINK COMMUNICATIONS INC, plaintiffs: [*2] Robert J. Weber, Attorney at Law, Chicago, IL.

For AMERITECH CORPORATION, defendant: Theodore A. Livingston, Matthew Aloysius Rooney, Christian Frederick Binnig, John E. Muench, Tyson J Covey, Mayer, Brown & Platt, Chicago, IL.

FEDERAL COMMUNICATIONS COMMISSION, amicus: Scott R. Lassar, United States Attorney's Office, Chicago, IL.

JUDGES: Blanche M. Manning, United States District Judge.

OPINION BY: Blanche M. Manning

OPINION

MEMORANDUM AND ORDER

For the purposes of this order, the court will assume familiarity with its May 18, 1998 order describing the teaming arrangement between defendant Ameritech Corporation and Qwest Communications International, Inc. In short, plaintiffs AT&T Corporation and MCI Telecommunications claim that this teaming arrangement violates *§§ 251(g)* and *271* of the Communications Act of 1934, as amended by the Telecommunications Act of 1996 (the "Act"). [1] AT&T has moved the court for an order vacating the court's prior referral of the plaintiffs' motion for a preliminary injunction to Magistrate Judge Guzman, immediately granting the plaintiffs' motion for a preliminary injunction, and referring issues arising from the Ameritech/Qwest alliance to the [*3] Federal Communications Commission. The FCC, who has filed a brief as amicus curiae, supports referral, while defendant Ameritech Corporation opposes AT&T's motions in their entirety.

1 The court notes that, on May 27, 1998, plaintiffs Association for Local Telecommunications Services, McLeodUSA Telecommunications Services, Inc., Focal Communications Corporation, KMC Telecom II, Inc., and NEXTLINK Communications, Inc. filed a joint notice of dismissal.

As explained more fully below, pursuant to the doctrine of primary jurisdiction, the court refers questions regarding the propriety of the Ameritech/Qwest alliance to the Federal Communications Commission, denies AT&T's renewed motion for a preliminary injunction, and stays this action pending further court order. In light of this ruling, the court terminates the referral of AT&T's motion for a preliminary injunction and discovery matters to Magistrate Judge Guzman.

I. Primary Jurisdiction

[HN1] Primary jurisdiction "applies where a claim is originally cognizable [*4] in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body." *U.S. v. Western Pacific Railroad Co., 352 U.S. 59, 63-64, 1 L. Ed. 2d 126, 77 S. Ct. 161 (1956)*. The Seventh Circuit has summarized the doctrine more succinctly as a principle that interrupts a suit "because it involves an issue . . . that Congress wants one of the administrative agencies to have first crack at." *City of Peoria v. General Electric Cablevision Corporation, 690 F.2d 116, 120 (7th Cir. 1982)*.

No fixed formula governs whether a court should refer a case under the doctrine of primary jurisdiction. *U.S. v. Western Pacific Railroad Co., 352 U.S. at 64*. Instead, [HN2] "in every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation." *Id.* Thus, when deciding whether the doctrine of primary jurisdiction applies, courts consider [*5] whether: (1) the issue presented is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise, and whether the issue presented is particularly within the agency's discretion; (2) whether a substantial danger of inconsistent rulings exists if the matter is not referred; and (3) whether the administration of justice favors

referral. *See, e.g., National Communications Association, Inc. v. AT&T, 46 F.3d 220, 222-23 (2d Cir. 1995)* (collecting cases). The Supreme Court has also directed that courts balance the advantages of applying the doctrine against the potential costs arising from delays in proceedings before the agency. *Ricci v. Chicago Mercantile Exchange, 409 U.S. 289, 321, 34 L. Ed. 2d 525, 93 S. Ct. 573 (1973).*

Ameritech opposes referral to the FCC, arguing that: (1) the FCC is no better situated than this court to consider the ramifications of the Ameritech/Qwest alliance because this case turns on the construction of a statute, and this kind of question is within the conventional competence of the court; (2) the facts presented by this case are not technical and thus the court [*6] will not benefit from the FCC's specialized knowledge; (3) referring this matter to ensure uniformity is unnecessary because the courts have mechanisms to address such concerns; and (4) the costs to Ameritech, Qwest and consumers outweigh any benefit that may exist. The court will discuss these arguments in the context of the four primary jurisdiction factors listed above.

A. Does the Ameritech/Qwest Alliance Involve Technical or Policy Considerations Within the FCC's Particular Field of Expertise?

Ameritech correctly notes that [HN3] statutory interpretation is within the conventional experience of judges. Nevertheless, if a case raises questions of fact outside the conventional experience of judges or involves the exercise of administrative discretion, "agencies created by Congress for regulating the subject matter should not be passed over." *Far East Conference v. U.S., 342 U.S. 570, 574, 96 L. Ed. 576, 72 S. Ct. 492 (1952).* This case turns on the interpretation of a novel arrangement between Ameritech and Qwest, under provisions of the Telecommunications Act that the FCC has not yet defined. *Cf. National Communications Association, Inc. v. AT&T, 46 F.3d at 223* (factual [*7] question regarding the plaintiff's timely payment of its bills did not present technical or policy issues).

As the Seventh Circuit has noted, in connection with the referral of a suit involving the cable television industry to the FCC, "the comprehensive regulatory responsibilities exercised by the FCC over the rapidly changing and economically and technologically complex cable television industry" militates in favor of allowing the agency to consider the matter in the first instance. *City of Peoria v. General Electric Cablevision Corporation, 690 F.2d at 121.* Certainly, these words are equally applicable to the new world and accompanying extensive regulatory framework created by the break-up of the Bell system.

The language of *47 U.S.C. § 251(g)*, which provides that the MJF's obligations remain in effect until superceded by FCC regulations, and *47 U.S.C. § 271(b)(1)*, which permits a Bell operating company and its affiliates to offer long distance services only with the FCC's permission, further supports the conclusion that Congress envisioned that the FCC would play a role in determining issues arising under those sections. *See Total Telecommunications Services, Inc. v.* [*8] *AT&T, 919 F. Supp. 472, 478 (D.D.C. 1996)* ("the powers granted to the FCC are a reflection of Congress' intention that one governmental entity be vested with the responsibility of developing, coordinating and enforcing a uniform telecommunications policy"), *aff'd by 99 F.3d 448 (1996)* (unpublished order); *Western Pacific, 352 U.S. at 65* (an agency's consideration of policy issues promotes the uniform and expert administration of the corresponding regulatory scheme). Moreover, where the resolution of a case hinges on "matters uniquely within the expertise and experience of an agency such as matters turning on an assessment of industry conditions," referral is especially appropriate. *Nader v. Allegheny Airlines, Inc., 426 U.S. 290, 304, 48 L. Ed. 2d 643, 96 S. Ct. 1978 (1976).* Thus, the court concludes that this factor favors referral.

B. Does a Substantial Danger of Inconsistent Rulings Exist if the Matter Is Not Referred?

The United States District Court for the Western District of Washington has referred an action arising from a teaming arrangement between U.S. West and Qwest Communications to the FCC. *See AT&T Corp. v. U.S. West Communications, Inc.*, No. [*9] C98-634WD (W.D. Wash. Jun. 4, 1998). The parties disagree as to whether this case and the Seattle case are factually similar. It is clear, however, that the legal issues -- the scope of *§§ 271* and 2519(g) -- are identical. Referral of these issues to the FCC would thus secure "uniformity and consistency in the regulation of business entrusted to [the FCC]" and would promote "a uniform and expert administration of the regulatory scheme laid down by the Act." *U.S. v. Western Pacific Railroad Company, 352 U.S. at 64-65*; *MCI Telecommunications Corp. v. AT&T,*

496 F.2d 214, 221 (3d Cir. 1974) (FCC proceedings addressing issues raised in a federal suit supported referral of that suit to the FCC to avoid conflict); *Total Telecommunications Services, Inc. v. AT&T, 919 F. Supp. at 478* (the doctrine of primary jurisdiction avoids contradictory rulings by the agency and the court).

Moreover, contrary to Ameritech's assertion that this case involves "garden variety legal questions" (Ameritech's opposition to referral to the FCC at 5), the court believes that this case raises important issues about permissible competition under the Act. Permitting the FCC to consider two permutations [*10] of teaming arrangements between local exchange carriers and long distance providers simultaneously will promote consistency in a matter of national importance (since the agency's views will be important, although not controlling, when the court ultimately considers the merits). *See Far East Conference v. U.S., 342 U.S. at 574-75.*

In addition, with the benefit of the agency's decision, the court believes it will be able to render a more informed decision. The court also notes that Ameritech's argument that the doctrine of primary jurisdiction impermissibly shifts the court's ability to decide cases to the executive branch is simply incorrect. [HN4] Referring a case to an agency simply allows the court to consider the agency's views when rendering its decision; it does not shift the power to determine a federal lawsuit to an administrative agency. *See City of Peoria v. General Electric Cablevision Corporation, 690 F.2d at 120* (primary jurisdiction doctrine enables "the agency to make a record and a decision on a matter before courts put their oar in"); *Johnson v. Artim Transportation System, Inc., 826 F.2d 538, 548 (7th Cir. 1987)* (primary jurisdiction doctrine does not affect [*11] court's power to consider a case); *Foremost Int'l Tours, Inc. v. Qantas Airways Ltd., 525 F.2d 281, 287 (9th Cir. 1975)* ("the court has the last word but it can properly seek the benefit of whatever contributions can be made by an agency whose 'area of specialization' embraces problems similar to or intermeshed with those presented to the court"). Thus, the court concludes that the danger of inconsistent rulings supports referral.

C. Does the Administration of Justice Favor Referral?

Counsel for the FCC has represented to the court that the FCC is focused on the issues presented by this case and intends to move with dispatch. The court does, however, recognize that referral will inherently cause some delay in the resolution of this case. Nevertheless, obtaining the agency's views on the ramifications of the Ameritech/Qwest teaming arrangement will allow the court to make a better-informed decision. The court also believes that rendering a decision without the benefit of the FCC's interpretation of the Act it is charged to interpret would be counterproductive. To put it another way, "a stitch in time saves nine." Thus, the administration of justice favors referral.

[*12] **D. Do the Advantages of Applying the Doctrine Outweigh the Potential Costs Arising from Delays in Proceedings Before the FCC?**

As noted above, referral will cause some delay. The court, however, accepts the assurances of the FCC that it will give this case high priority and make every effort to conclude its proceedings as soon as possible. The minimal delay occasioned by referral is less weighty than the need to provide the court with the benefit of the agency's views and to allow the agency to play the role envisioned by Congress. Moreover, the court fundamentally disagrees with Ameritech's argument that the FCC's consideration of the Ameritech/Qwest arrangement will not bring anything new to the table.

In sum, the nature of the issues presented in this case, the risk of inconsistent interpretations of the Act, the administration of justice, and the balance of delay versus the advantages of applying the primary jurisdiction doctrine militate in favor of a referral to the FCC. Accordingly, AT&T's request to refer issues arising from the Ameritech/Qwest alliance to the Federal Communications Commission is granted.

II. AT&T's Renewed Motion for a Preliminary Injunction

[*13] For the reasons explained in the court's May 18, 1998 order, this court has the power to grant injunctive relief to the plaintiffs. Ameritech and AT&T disagree as to the impact that referral of this case to the FCC has on the court's authority to issue injunctive relief. Ameritech contends that entry of interim relief would subvert the goals of the primary jurisdiction doctrine by undercutting an agency's ability to consider the matter in the first instance. It also contends that AT&T is judicially estopped from abandoning its prior adherence to this position.

In response, AT&T contends that: (1) the FCC has already expressed a view on the merits and thus ruling on the preliminary injunction motion would not step on the FCC's toes; (2) the FCC's belief that this case presents "substantial" and "serious" questions means that the court need not reach the merits of this case to decide its motion for a preliminary injunction; (3) the FCC does not object to the entry of a preliminary injunction prior to a referral; (4) it now only seeks an interim injunction until the FCC issues its decision; and (5) denial of injunctive relief due to the referral would create a "near certainty of irreparable [*14] harm" (AT&T's reply memorandum at 6) because the FCC is institutionally incapable of acting quickly.

[HN5] The doctrine of primary jurisdiction affects the wisdom of entering injunctive relief prior to agency action. It does not, however, deprive the court of the power to order injunctive relief. *Atchison, Topeka & Santa Fe Railway Co. v. Wichita Board of Trade, 412 U.S. 800, 820, 37 L. Ed. 2d 350, 93 S. Ct. 2367 (1973)* (noting that no "provision in the relevant statutes deprives federal courts of their general equitable power to preserve the status quo to avoid irreparable harm pending review.") Nevertheless, courts should generally avoid expressing a view on the merits when referring a case to an agency under the primary jurisdiction doctrine. *See, e.g., Total Telecommunications Services, Inc. v. AT&T, 919 F. Supp. at 483* (declining to entertain the plaintiffs' request for injunctive relief after invoking the doctrine of primary jurisdiction "because to engage in an analysis of whether injunctive relief should issue in this case, would require the court to analyze the underlying merits of the case, thereby encroaching into the FCC's primary jurisdiction.")

As the Supreme Court [*15] explained in *Atchison, Topeka & Santa Fe Railway Co.*, a case arising from an Interstate Commerce Commission order governing inspection charges:

> National transportation policy reflects many often-competing interests. Congress has established an administrative agency that has developed a close understanding of the various interests and that may draw upon its experience to illuminate, for the courts, the play of those interests in a particular case. [citations omitted]. Ordinarily, then, a court should refrain from expressing a preliminary view on what national transportation policy permits, before the ICC expresses its view. But when a court issues an injunction pending final determination, one important element of its judgment is its estimate of the probability of ultimate success on the merits by the party challenging the agency action. *Virginia Petroleum Jobbers Assn. v. FPC, 104 U.S. App. D.C. 106, 259 F.2d 921, 925 (1958)*. Depending on the type of error the reviewing court finds in the administrative proceedings, the issuance of an injunction pending further administrative action may indicate what the court believes is permitted by national transportation policy, [*16] prior to an expression by the Commission of its view. This is precisely what the doctrine of primary jurisdiction is designed to avoid.

Id. at 820-21.

With these principles in mind, the court turns to AT&T's arguments. First, interpreting the FCC's statement that this case presents "substantial" and "serious" questions as a ruling on the merits is an unfounded stretch. The FCC's amicus brief is based on its belief that it should consider the issues presented by this case in the first instance. The FCC has also advised the court that FCC orders cited by Ameritech and previously considered by the court were not meant to cover the teaming arrangement presented by this case. It is thus clear that the FCC has not reached a decision on the merits.

Moreover, the FCC's statement that this case presents "substantial" or "serious" questions goes to the importance of the issues raised in this case and the concomitant wisdom of allowing the FCC to provide the court with its views regarding the teaming agreement. Again, however, it does not mean that the FCC has already reached a decision on the merits. Accordingly, interposing the court's views on the merits would be inconsistent [*17] with the goals of the primary jurisdiction doctrine.

Second, AT&T argues that entry of a preliminary injunction is warranted based on the FCC's belief that this case presents "substantial" and "serious" questions, and

that the FCC's statements obviate the need for the court to reach the merits. As noted above, the FCC has not rendered a merits decision, so the court is in the same position that it was in when it denied AT&T's motion for a temporary restraining order. In any event, AT&T has not provided the court with any authority supporting the proposition that, if the FCC states that a case presents important issues, a plaintiff is entitled to injunctive relief, and the court is not aware of any authority supporting this position.

Third, AT&T argues that the court should grant its motion for a preliminary injunction because the FCC does not object to the entry of a preliminary injunction prior to a referral. This argument is, again, based on an overly expansive reading of the FCC's statements. The FCC advised the court that it took no position on the propriety of issuing a preliminary injunction. Declining to take a position on a motion is not synonymous with supporting the granting [*18] of that motion.

Fourth, AT&T argues that it only seeks an interim injunction until the FCC issues its decision. This concession, however, is not relevant to the question of whether AT&T has established that it is entitled to injunctive relief in the first place. In any event, [HN6] the FCC has the authority to issue interim injunctive relief. *See 47 U.S.C. § 154(i)* (the FCC may issue "such orders, not inconsistent with this [Act], as may be necessary in the execution of its functions"); *U.S. v. Southwestern Cable Co., 392 U.S. 157, 181, 20 L. Ed. 2d 1001, 88 S. Ct. 1994 (1968)* (pursuant to *§ 154(i)*, the FCC may grant interim relief). Thus, this argument is unavailing.

Fifth, AT&T argues that denial of injunctive relief due to the referral would create a "near certainty of irreparable harm" because the FCC is institutionally incapable of acting quickly. These concerns, while valid in light of the delay traditionally associated with administrative proceedings, appear to be unnecessary in light of the FCC's express representations that it will consider this case, as well as any requests for interim relief, expeditiously. Moreover, this court retains the power to revisit this issue [*19] if the FCC fails to live up to its promises. *See Richman Brothers Records, Inc. v. U.S. Sprint Communications Co., 953 F.2d 1431, 1448 (3d Cir. 1991).*

In essence, a decision to defer consideration of the plaintiffs' request for a preliminary injunction simply shifts the initial consideration of that request to the FCC, if the plaintiffs renew their request for an injunction before the agency. As the FCC is uniquely situated to render a decision on the plaintiffs' likelihood of success on the merits, allowing the FCC to consider the plaintiffs' request comports with the systemic concerns supporting a referral under the primary jurisdiction doctrine.

For these reasons, the court concludes that it has the power to order injunctive relief. Nevertheless, the court, in the exercise of its discretion, declines to do so, because the court has referred this matter to the FCC. Thus, any further comments regarding the merits would be inappropriate.

III. In Light of the Referral to the FCC, Should the Court Stay or Dismiss This Action?

The parties's briefs do not address whether this action should be stayed or dismissed pending the FCC's consideration of the Ameritech/Qwest alliance. [HN7] [*20] A court may, in its discretion, stay proceedings and retain jurisdiction pending determination by an administrative agency pursuant to the doctrine of primary jurisdiction. If the parties would not be unfairly disadvantaged, the court may also dismiss the case without prejudice. *Reiter v. Cooper, 507 U.S. 258, 268-69, 122 L. Ed. 2d 604, 113 S. Ct. 1213 (1993); U.S. v. Michigan National Corp., 1974 U.S. Dist. LEXIS 12205 (1974).* To avoid any possible prejudice to the plaintiffs, the court will stay this action, rather than dismiss it. Retention of jurisdiction over this case will allow the court to revisit AT&T's request for interim relief if the FCC fails to live up to its promises.

IV. Conclusion

Pursuant to the doctrine of primary jurisdiction, AT&T's motion to refer issues arising from the Ameritech/Qwest alliance to the FCC is granted. These matters are hereby referred to the FCC and this action is stayed pending further court order. In light of this ruling, the court terminates the referral of AT&T's motion for a preliminary injunction and discovery matters to Magistrate Judge Guzman. AT&T's renewed motion for a preliminary injunction is denied. [*21] The parties are directed to provide the court with a joint written status report on the progress of this case before the FCC by July 9, 1998.

DATE: JUN 9 1998

Blanche M. Manning United States District Judge

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Send To: TRUMMEL, RACHAEL
BARACK FERRAZZANO KIRSCHBAUM & NAGELBERG
200 WEST MADISON STE. 3900
CHICAGO, IL 60606-3465